The Examiner has rejected claims 7-9, 12-14, 17-19 and 22-24 under 35 U.S.C. §112, second paragraph, asserting that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner has rejected claims 7-9, 12-14, 17-19 and 22-24 under 35 U.S.C. §112, first paragraph, asserting that the specification, while being enabling for induction of antibody response, does not reasonably provide enablement for transformation of cells in inducing a protective response (vaccine).

The Examiner has rejected claims 7-9 under 35 U.S.C. §102(a) asserting that the claims are clearly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Meehan et al. (J. of Gen. Virology, 1997, vol. 78, pp. 221-227).

The Examiner has rejected claims 7-9, 12-14, 17-19 and 22-24, under 35 U.S.C. §103(a) asserting the claims are unpatentable over Meehan et al., (J. of Gen. Virology, 1997, vol. 78, pp. 221-227) and Vogel et al. (Clinical Microbiology Review, 1995, Vol. 8, No. 3, pp. 406-410).

These rejections are believed to be overcome in part by the amendments and are otherwise traversed for reasons discussed below.

Overview of the Amendments

The amendment to claim 7 has been made without prejudice or disclaimer. Applicants expressly reserve the right to bring the subject matter of the original claim again in a subsequent, related application.

The Examiner has objected to the specification because "the date and the designated accession number for the deposited virus are missing from the specification on page 8, lines 29, and 30." The specification has been amended to introduce the information per the Examiner's request.

Basis for the amendment to claim 7 ("isolated polynucleotide") can be found throughout the specification, for example, at the following locations: originally presented

claim 1; and, page 12, lines 25-32 .

Basis for the amendment to claim 7 ("selectively hybridizing") can be found throughout the specification, for example, at the following locations: originally presented claim 1; and, page 18, line 28, to page 19, line 12.

Accordingly, no new matter has been added by way of this amendment and the entry thereof is respectfully requested.

Addressing the Examiner's Objections and Rejections

1. Election/Restriction

Applicants confirm election, with traverse, of Group II, claims 7-9, 12-14, 17-19, and 22-24. By the amendment, Applicants cancel claims 1-6, 10, 11, 15, 16, 20, 21, and 25-47, without prejudice or disclaimer. Applicants expressly reserve the right to bring the subject matter of the original claims again in a subsequent, related application.

2. Objections to the Specification

The Examiner has objected to the specification because "the date and the designated accession number for the deposited virus are missing from the specification on page 8, lines 29, and 30." The Examiner has requested correction.

Applicants do not see any such missing deposit information on page 8; however, such material is missing on page 61, lines 29-30. The specification has been amended to include the appropriate ATCC deposit information. Accompanying this amendment is the ATCC *International Form* confirming deposit of the Porcine circovirus type II full length viral DNA.

No new matter has been added by way of this amendment, and the entry thereof is respectfully requested.

3. Rejection of Claims 7-9, 12-14, 17-19 and 22-24 under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 7-9, 12-14, 17-19 and 22-24 under 35 U.S.C. §112, second paragraph, asserting that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner has asserted the following specific deficiencies in the claims.

A. The Office alleges that claims 7-9 are vague and indefinite, that the claims are very confusing, and that the metes and bounds of the derived polypeptide(s) is/are not defined.

Contrary to the Examiner's assertion, the metes and bounds of the invention are clearly defined by claims 7-9. The Examiner asserts that "(T)he metes and bounds of the derived polypeptide(s) is/are not defined The intended derived polypeptide should be identified." First, the term "derived from" is defined in the specification, at least at, pages 9-12. Examples of "derived" polypeptides are provided throughout the specification, for example, page 10, lines 15-21, page 11, lines 21-24, pages 24-26; and page 30, lines 3-16.

Second, the claims clearly recites the limitations of the claimed isolated polynucleotide. It comprises, (i) a polynucleotide encoding an immunogenic porcine circovirus Type II (PCVII) polypeptide, where (ii) the polynucleotide is capable of selectively hybridizing to a procine circovirus Type II (PCVII) nucleotide sequence. Selectively hybridizing was defined in the specification, for example, at page 18, lines 27, to page 19, lines 12. Further, the polypeptide encoded by the polynucleotide has at least about 85% identity to a polypeptide selected from the group consisting of a polypeptide derived from (a) open reading frame (ORF) 1 (SEQ ID NO:3), (b) ORF 2 (SEQ ID NO:9), (c) ORF 3 (SEQ ID NO:7), (d) ORF 4 (SEQ ID NO:20), (e) ORF 5 (SEQ ID NO:21), (f) ORF 6 (SEQ ID NO:5), and (g) immunogenic fragments of (a)-(f) comprising at least about 5 amino acids. Percent identity was defined in the specification, at least at,

page 17, line 20, to page 18, line 27. Immunogenic polypeptides were defined in the specification, at least at, page 14, line 9, to page 15, line 2. Further, immunogenic fragments were defined in the specification, at least at, page 15, lines 11-19.

The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the "definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). A claim which is clear to one ordinarily skilled in the art when read in light of the specification, does not fail for indefiniteness. *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F2d 1453, 1 USPQ2d 1536 (Fed. Cir 1986).

In view of the above amendments, the teachings of the specification and the level of ordinary skill in the present art, the applicants submit that the boundaries of the claims are capable of being understood by one of ordinary skill in the art. Therefore, the rejection of the claims under 35 U.S.C. §112, second paragraph, should be withdrawn.

B. The Office alleges that claims 17-19 are confusing. The Examiner states that "this affects the dependent claims." In this regard it is unclear to applicants what the Examiner intends, in that, there are no pending claims dependent on claims 17-19. Clarification is requested. Further, the Examiner has questioned whether the claims "read on gene therapy or DNA vaccines," and "the induction of immune response."

It is unclear to the applicants why the Examiner is trying to read limitations into the claims. A claim need not "describe" the invention, such description is the role of the disclosure portion of the specification and not the role of the claims. *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 806 F.2d 1565, 1 USPQ 2d 1801, 1088. The applicants submit that the language of the claims is clear. The claims are directed to host cells transformed with a recombinant vector. Applicants believe that one of ordinary skill in the art would understand the claim as read in light of the specification. For example, the specification

teaches production of PCVII proteins using transformed cells (pages 24-29), and *in vivo* and *ex vivo* transfection of a subject's cells (e.g., page 48). A claim which is clear to one ordinarily skilled in the art when read in light of the specification, does not fail for indefiniteness. *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F2d 1453, 1 USPQ2d 1536 (Fed. Cir 1986).

In view of the above amendments and comments the Applicants submit that the claims comply with the requirements of 35 U.S.C. §112, second paragraph, and that the rejection of the claims should be withdrawn.

4. Rejection of Claims 7-9, 12-14, 17-19 and 22-24 under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 7-9, 12-14, 17-19 and 22-24 under 35 U.S.C. §112, first paragraph, asserting that the specification, while being enabling for induction of antibody response, does not reasonably provide enablement for transformation of cells in inducing a protective response (vaccine).

The Examiner is reading limitations into the claims which are not present. None of claims 7-9, 12-14, 17-19, or 22-24 recite a "vaccine." The Examiner asserts that "(T)he current specification does not teach nor enables a vaccine to induce a protective response wherein upon introduction of the specific antigens or fragments thereof in to the host a protective response can be inferred. Absent teaching by the specification it would require undue experimentation for one ordinary skill in the art to enable the scope of the claims." Office action page 5, lines 6. Even if, *arguendo,* the specification is not enabling for "vaccines", the specification is enabling for a wide variety of applications including, but not limited to, diagnostic assays (e.g. pages 38-46), the production of antibodies reactive with the novel virus of the present invention (e.g., pages 30-32), and the production of polypeptides derived from PCVII (e.g., pages 24-29).

The standard for enablement is not that "all" possible species are exemplified and operable. Merely pointing out that a claim is broad, in that it reads on undisclosed as well as disclosed embodiments is not sufficient. The mere fact that a claim embraces

undisclosed or inoperative species or embodiments does not necessarily render it unduly broad. *Horton v. Stevens*, 7 USPQ2d 1245, 1247 (Fed. Cir. 1988). The law does not require an applicant to describe in his specification every conceivable embodiment of the invention. *SRI International v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 227 USPQ 577 (Fed. Cir. 1985). Accordingly, applicants submit that the scope of the invention is clearly enabled by the teachings of the specification and the abilities of one having ordinary skill in the art.

The Examiner goes on to assert "(T)he specification provides no teaching as to the transformation and induction of immunogenic protective response against the claimed antigenic fragments." Office action, page 5, lines 6-7. This assertion is incorrect. The specification discusses vaccine formulations and administration, for example, at pages 32- 38. Further, the enablement requirement may be satisfied even though some experimentation is required. *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d at 1367, 231 USPQ 81 (Fed. Cir. 1986).

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*Ex parte Forman*, 230 USPQ 546 (P.T.O. Bd. Pat. App. & Int., 1986).

The Examiner has not objected that one of ordinary skill in the art could not recreate the invention; rather, the Examiner has focused on the "vaccine" embodiment of the present invention. Moreover, the Examiner has merely asserted, and has not shown, that an undue amount of experimentation would be necessary to replicate the claimed invention. For example, the Examiner asserts that "(T)herefore considering the large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the invention." (Office action, page 5, lines 7-10). Whenever the PTO makes such a rejection for failure to teach and/or use the invention, the PTO must explain its reasons for the rejection and support the rejection with (i) acceptable evidence, or (ii) reasoning which contradicts the applicants' claim: the reasoning must be supported by

current literature as a whole and the PTO must prove the disclosure requires undue experimentation. *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971). The Examiner has provided no such support for the present rejection.

In view of the above arguments and amendments, the applicant submits that the claims are enabled and that the rejection of the claims under 35 U.S.C 112, first paragraph, should be withdrawn.

5. Rejection of Claims 7-9 Under 35 U.S.C. §102(a)

The Examiner has rejected claims 7-9 under 35 U.S.C. §102(a) asserting that the claims are clearly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Meehan et al. (J. of Gen. Virology, 1997, vol. 78, pp. 221-227).

The Examiner's rejection of the claims in the alternative is incorrect. The Examiner asserts anticipation or *prima facie* obviousness. However, the Examiner goes on to use the same reference (Meehan, et al.) in combination with further references to reject the same claims (i.e., 7-9; see section 6, below). Accordingly, the rejection under §103(a) will be discussed below and only the rejection of claims 7-9 under 35 U.S.C. §102(a) will be addressed under this section.

For prior art to anticipate under 35 U.S.C. 102 it has to meet every element of the claimed invention: such a determination is one of fact. *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d at 1367, 231 USPQ 81 (Fed. Cir. 1986). The pending claims are directed to an isolated polynucleotide, comprising a polynucleotide encoding an immunogenic porcine circovirus Type II (PCVII) polypeptide, said polynucleotide capable of **selectively hybridizing** to a procine circovirus Type II (PCVII) nucleotide sequence. The reference relied upon by the Examiner teaches only a porcine circovirus Type I. Further, as defined in the specification "(T)wo nucleic acid fragments are considered to be 'selectively hybridizable' to a PCVII polynucleotide, if they are capable of specifically hybridizing to a PCVII nucleic acid or a variant thereof (e.g., a probe that hybridizes to a PCVII nucleic acid but not to polynucleotides from other members of the circovirus family)." Specification, page 18, lines 28-34.

Accordingly, in view of the above arguments and amendments the reference of Meehan, et al., cannot be said to anticipate the claimed invention. Applicants respectfully request withdrawal of the rejection of the claims under 35 U.S.C. §102(a).

6. Rejections of the Claims Under 35 U.S.C. §103

The Examiner has rejected claims 7-9, 12-14, 17-19 and 22-24, under 35 U.S.C. §103(a) asserting the claims are unpatentable over Meehan et al., (J. of Gen. Virology, 1997, vol. 78, pp. 221-227) and Vogel et al. (Clinical Microbiology Review, 1995, Vol. 8, No. 3, pp. 406-410).

The Examiner asserts the following:

"Meehan et al disclosed the complete nucleotide sequence of porcine circovirus. They further disclosed the genomic organization of the PCV genome (see the abstract, and page 223, right paragraph). This differs since they did not teach a vector and expression nucleic acids." Office action, page 7, lines10-13.

The Examiner has failed to establish a case of *prima facie* obviousness. The Examiner has not accurately addressed the differences between the prior art and the claims at issue. *Graham v. John Deere Co.,* 383 U.S.C. 1, 86 S. Ct. 684, 15 L Ed2d 545, 148 USPQ 459 (Supreme Court, 1966). For example, the claims of the present application are directed to an isolated polynucleotide, comprising a polynucleotide encoding an immunogenic porcine circovirus Type II (PCVII) polypeptide. An important difference between the cited prior art the present claims is that the cited prior art teaches the polynucleotide sequence of a porcine circovirus Type I. Differences between these two viruses are noted throughout the specification (see, for example, Figures 3A-3D and 4A-4B). The pending claims also recited the limitation that the polynucleotide is capable of selectively hybridizing to a procine circovirus Type II (PCVII) nucleotide sequence. As noted above, two nucleic acid fragments are considered to be "selectively hybridizable" to a PCVII polynucleotide, if they are capable of specifically hybridizing to a PCVII nucleic acid or a variant thereof (e.g., a probe that hybridizes to a PCVII nucleic acid **but not to polynucleotides from other members of the circovirus family**, such

other members include the PCVI polynucleotide taught by Meehan, et al.) The secondary reference (Vogel, et al.) contains no teachings regarding the circovirus genome (see, Office action, page 7, lines 15-16) and thus fails to make up for the shortcomings of the primary reference.

Accordingly, the Examiner has failed to teach the elements of the present invention and has not established a case of *prima facie* obviousness.

Independent claim 7 recites the limitation that the polynucleotide is capable of selectively hybridizing to a procine circovirus Type II (PCVII) nucleotide sequence. All further pending claims are ultimately dependent on claim 7, and thus at least distinguish over the prior art in view of their dependence on claim 7. Dependent claims are non-obvious under 35 U.S.C. §103 if claims from which they depend are non-obvious. *In re Fine*, 837 F.2d 1071, 5 USPQd2 1596, 1600 (Fed. Cir. 1988).

In view of the above amendments and arguments, the applicants submit that the rejections under 35 U.S.C. §103 are inappropriate and should be withdrawn.

CONCLUSION

Applicant respectfully submits that the claims comply with the requirements of 35 U.S.C. §112 and define an invention that is patentable over the art. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Respectfully submitted,

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enclosure: ATCC *International Form* confirming deposit of the Porcine circovirus type II full length viral DNA